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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/053,510	01/17/2002	Julie D. Saba	200116.402C2	3135

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EXAMINER	
RAMIREZ, DELIA M	

ART UNIT	PAPER NUMBER
1652	9

DATE MAILED: 11/04/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/053,510	SABA ET AL.	
	Examiner	Art Unit	
	Delia M. Ramirez	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 4-6 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 4-6 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 6 .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Status of the Application

Claims 4-6 are pending.

Applicant's election without traverse of Group II, claims 4-6 drawn to a method for identifying an agent that modulates sphingosine-1-phosphate lyase activity, in Paper No. 8, filed on 3/25/2003 is acknowledged.

Priority

1. Acknowledgment is made of a claim for domestic priority under 35 U.S.C. 120 or 121 to US application No. 09/356,643 filed on 07/19/1999, and 08/939,309 filed on 09/29/1997. However, Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120 as follows. An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification of in an application data sheet (37 CFR 1.78(a)(2) and (a)(5)). The specific reference to any prior nonprovisional application must include the relationship (i.e., continuation, divisional, or continuation-in-part) between the applications except when the reference is to a prior application of a CPA assigned the same application number.

2. It is noted that the polynucleotide of SEQ ID NO: 7 and the polypeptide of SEQ ID NO: 8 were first disclosed in U.S. Application No. 08/939,309 filed on 09/29/1997 as SEQ ID NO: 3 and SEQ ID NO: 4, respectively.

Information Disclosure Statement

3. The information disclosure statement (IDS) submitted on 1/17/2002 is acknowledged. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Claim Rejections - 35 USC § 112, First Paragraph

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 4-6 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method for identifying an agent that modulates the sphingosine-1-phosphate lyase activity of the polypeptide of SEQ ID NO: 8, does not reasonably provide enablement for a method for identifying an agent that modulates the sphingosine-1-phosphate lyase activity of a structural (i.e. sequence) homolog of the polypeptide of SEQ ID NO: 8. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The criteria for undue experimentation, summarized in *re Wands*, 8, USPQ2nd 1400 (Fed. Cir. 1988) are: 1) quantity of experimentation necessary, 2) the amount of direction or guidance presented, 3) the presence and absence of working examples, 4) the nature of the invention, 5) the state of prior art, 6) the relative skill of those in the art, 7) the predictability or unpredictability of the art, and 8) the breath of the claims.

Claims 4-6 are directed to a method for identifying an agent that modulates the sphingosine-1-phosphate lyase activity of 70-90% sequence homologs of the polypeptide of SEQ ID NO: 8. The scope of the claims is not commensurate with the enablement provided in regard to the large number of unknown sphingosine-1-phosphate lyases encompassed by the claims. While the specification discloses the structure and function of the polypeptide of SEQ ID NO: 8 and also teaches other sphingosine-1-phosphate lyases, the specification fails to disclose the critical structural elements required in any polypeptide to display sphingosine-1-phosphate lyase activity or the amino acids which can be modified (i.e. substituted, deleted or inserted) in the polypeptide of SEQ ID NO: 8 to obtain a 70-90% structural homolog of the polypeptide of SEQ ID NO: 8 which retain sphingosine-1-phosphate lyase activity.

While the argument can be made that the specification is enabling for all the structural homologs recited in the claims since one could isolate/make other polypeptides of similar function based on structural homology using those structures disclosed by the specification and those of the prior art, the state of the art teaches the unpredictability of assigning function based on structural homology and how small structural changes can result in major changes in function. Witkowski et al. (Biochemistry 38:11643-11650, 1999) teaches that one amino acid substitution transforms a β-ketoacyl synthase into a malonyl decarboxylase and completely eliminates β-ketoacyl synthase activity. Van de Loo et al. (Proc. Natl. Acad. Sci. 92:6743-6747, 1995) teaches that polypeptides of approximately 67% homology to a desaturase from *Arabidopsis* where found to be hydroxylases once tested for activity. Seffernick et al. (J. Bacteriol. 183(8):2405-2410, 2001) teaches that two naturally occurring Pseudomonas enzymes having 98% amino acid sequence identity catalyze two different reactions: deamination and

dehalogenation, therefore having different function. Broun et al. (Science 282:1315-1317, 1998) teaches that as few as four amino acid substitutions can convert an oleate 12-desaturase into a hydrolase and as few as six amino acid substitutions can transform a hydrolase to a desaturase. Since structure determines the function of a polypeptide, one would require some knowledge or guidance as to how structure correlates with function to isolate/make the polypeptides required to practice the claimed method. Therefore, due to the lack of relevant examples, the amount of information provided, the lack of knowledge about the critical structural elements required to maintain the desired function, and the unpredictability of the prior art in regard to function based on homology, one of ordinary skill in the art would have to go through the burden of undue experimentation in order to screen and isolate those polypeptides, as encompassed by the claim, with sphingosine-1-phosphate lyase activity, to practice the claimed method. Thus, Applicant has not provided sufficient guidance to enable one of ordinary skill in the art to make and use the invention in a manner reasonably correlated with the scope of the claims.

Double Patenting

6. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

7. Claims 4-6 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 11-12 of copending Application No. 10/197,073. An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim not is patentably distinct from the reference claim(s) because the examined claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985). Although the conflicting claims are not identical, they are not patentably distinct from each other. Claim 11 of copending Application No. 10/197,073 is directed in part to a method for identifying an agent that modulates sphingosine-1-phosphate lyase activity wherein the method comprises the steps of (1) contacting a candidate agent with a polypeptide 100% identical to that of SEQ ID NO: 8 of the instant application, and (2) measuring the ability of the polypeptide to degrade sphingosine-1-phosphate in the presence and absence of said candidate agent. Claim 12 of copending Application No. 10/197,073 is also directed to the method as described above with the added limitation that the candidate agent is incubated with a cell capable of expressing the polypeptide, and wherein measuring the ability to degrade sphingosine-1-phosphate is performed using an in vitro assay and a cellular extract. Claim 4 of the instant application is directed in part to a method for identifying an agent that modulates the sphingosine-1-phosphate lyase activity of the polypeptide of SEQ ID NO: 8 which comprises contacting a candidate agent with said polypeptide and measuring the ability of the polypeptide to degrade sphingosine-1-phosphate in

the presence and absence of said candidate agent. Claim 5 of the instant application is directed to the method as described above with the added limitation that the candidate agent is incubated with a cell expressing said polypeptide and wherein measuring the ability to degrade sphingosine-1-phosphate is performed using an in vitro assay and a cellular extract. Claim 6 of the instant application is directed to the method of claim 5 with the added limitation that the cell is transformed with a recombinant expression vector comprising the polynucleotide of SEQ ID NO: 7 (encoding the polypeptide of SEQ ID NO: 8). Therefore, claims 11-12 of copending Application No. 10/197,073 would anticipate claims 4-5 of the instant application as written. Claim 6 of the instant application would be obvious over claim 12 of copending application No. 10/197,073 in view of the fact that cell transformation with an expression vector comprising the polynucleotide encoding the polypeptide in order to produce the protein of interest is well known and widely used in the art.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

8. Claims 4-6 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 11-12 of copending Application No. 10/286175. An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim not is patentably distinct from the reference claim(s) because the examined claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed.

Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985). Although the conflicting claims are not identical, they are not patentably distinct from each other. Claim 11 of copending Application No. 10/286175 is directed in part to a method for identifying an agent that modulates sphingosine-1-phosphate lyase activity wherein the method comprises the steps of (1) contacting a candidate agent with a polypeptide 100% identical to that of SEQ ID NO: 8 of the instant application, and (2) measuring the ability of the polypeptide to degrade sphingosine-1-phosphate in the presence and absence of said candidate agent. Claim 12 of copending Application No. 10/286175 is also directed to the method as described above with the added limitation that the candidate agent is incubated with a cell capable of expressing the polypeptide, and wherein measuring the ability to degrade sphingosine-1-phosphate is performed using an in vitro assay and a cellular extract. Claim 4 of the instant application is directed in part to a method for identifying an agent that modulates the sphingosine-1-phosphate lyase activity of the polypeptide of SEQ ID NO: 8 which comprises contacting a candidate agent with said polypeptide and measuring the ability of the polypeptide to degrade sphingosine-1-phosphate in the presence and absence of said candidate agent. Claim 5 of the instant application is directed to the method as described above with the added limitation that the candidate agent is incubated with a cell expressing said polypeptide and wherein measuring the ability to degrade sphingosine-1-phosphate is performed using an in vitro assay and a cellular extract. Claim 6 of the instant application is directed to the method of claim 5 with the added limitation that the cell is transformed with a recombinant expression vector comprising the polynucleotide of SEQ ID NO: 7 (encoding the polypeptide of SEQ ID NO: 8). Therefore, claims 11-12 of copending Application No. 10/197,073 would anticipate claims 4-5 of the instant application as written.

Claim 6 of the instant application would be obvious over claim 12 of copending application No. 10/197,073 in view of the fact that cell transformation with an expression vector comprising the polynucleotide encoding the polypeptide in order to produce the protein of interest is well known and widely used in the art.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

9. No claim is in condition for allowance.

10. Certain papers related to this application may be submitted to Art Unit 1652 by facsimile transmission. The FAX number is (703) 308-4556. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 CFR 1.6(d)). NOTE: If Applicant submits a paper by FAX, the original copy should be retained by Applicant or Applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED, so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Delia M. Ramirez whose telephone number is (703) 306-0288. The examiner can normally be reached on Monday-Friday from 8:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Ponnathapura Achutamurthy can be reached on (703) 308-3804. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Delia M. Ramirez, Ph.D.
Patent Examiner
Art Unit 1652

DR
October 16, 2003

REBECCA E. PROUTY
PRIMARY EXAMINER
GROUP ~~1900~~ 1600